



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,404	09/08/2000	Weimin Sun	279.279US1	3413

21186 7590 04/08/2003

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 04/08/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,404

Applicant(s)

SUN ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/10/03 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 7, 9-11, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

“Long-term maximum” in claim 7 is unclear and “the long-term maximum exertion level” in claim 9 (line 3), claim 10 (line 3), claim 11 (line 5) lacks antecedent basis. These rejections appear correctable by changing claim 3 at line 3 from “long-term maximal” to --long-term-maximum--.

In claim 11, line 7, “the slope” lacks antecedent basis.

In claim 23 (line 3) and claim 24 (line 3), “the long-term maximum exertion level” lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. Claims 1-25 stand rejected under 35 U.S.C. 102(e) as being anticipated by Kay et al. (US 6411850).

Kay et al. disclose a method for automatically determining an anaerobic breakpoint for an adaptive rate pacemaker and for automatically adjusting the pacing rate based on the slope of the rate responsive curve. The cardiac pacemaker pacing signal is modified by the sensed ventilation and the pacing rate is modified in response to ventilatory breakpoint. The control circuit matches the peak ventilation, read as the MAR, with the maximum pacing rate

(col. 3 @ 13-30). Once the breakpoint is reached, the pulse is attenuated based on the rate response slope (col. 5 @ 10-44; col. 7 @ 20-37; figure 1). The dual slope curve of the respiratory rate (figure 1) and the breakpoint, read as the MSR, can be determined from data collected over a period of time to define the respiratory reserve by measuring ventilation during exercise (col. 2 @ 48-65; col. 7 @ 20-24). The breakpoint and curve can also be determined using a pacemaker programmed to determine the ventilatory threshold and peak ventilation which then matches the peak ventilation to the maximal pacing rate (col. 7 @ 1-10). Short-term average relative minute ventilation, 30 second, and long-term average relative minute ventilation, 2 hour, are used to regulate the sensor rate in correspondence to metabolic demand using a Response Factor (col. 8 @ 22-42). The Response Factor slope, which maps the patient's respiratory reserve, is dynamically adjusted based on the maximum daily sensor rate excursions and a weekly average of these readings (col. 8 @ 43-61). Historically, a fixed percentage of the respiratory reserve is noted as a means used to adjust the pacing rate (col. 8 @ 54-57).

The Applicant's arguments filed 2/10/03 have been fully considered, but they are not convincing.

The Applicant states he is unable to find a method for operating a rate adaptive pacemaker in which a rate responsive curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR, the sensor indicated rate is limited to a specific maximum sensor indicated rate MSR that is independent from the MAR, and the MSR is increased after a specified time period during which the long-term maximum exertion level is updated. The Examiner finds Kay

et al. do teach these elements of the claimed invention as follows: Kay et al. teach method for operating a rate adaptive pacemaker (col. 1 @ 7-10) in which a rate responsive curve is defined (figure 1; col. 5 @ 11-44) such that an exertion level corresponding to the patient's maximum exercise capacity (figure 1; Peak Exercise - MVpeak) would be mapped to a physiologically favorable maximum rate, MAR (figure 1; Paced Rate at Anaerobic Threshold - PRat), the sensor indicated rate is limited to a specific maximum sensor indicated rate MSR (figure 1; Maximum Sensor Rate) that is independent from the MAR, and the MSR is increased after a specified time period during which the long-term maximum exertion level is updated (col. 8 @ 43-53).

The Applicant apparently traverses reading the peak ventilation as the MAR and cites the instant specification (page 16, lines 3-6) for clarification of the MAR. The instant specification states the MAR is a maximal rate that is deemed physiologically favorable. The ventilation rate is read to favorably reflect the exertion level, hence Kay et al. are deemed to read on the claimed invention.

Statutory Basis

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
3/30/03

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700